PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Case 21854 WO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/007367	International filing date *(day/month/year)* 06.07.2004	Priority date *(day/month/year)* 15.07.2003
International Patent Classification (IPC) or national classification and IPC A23C9/20, A23J3/32, A23K1/00, A23K1/16, A23L1/30		
Applicant DSM IP ASSETS B.V.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
13.05.2005	13.12.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Rooney, K Telephone No. +31 70 340-3931

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/007367

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-6 as originally filed

   Claims, Numbers

   1-17 received on 13.05.2005 with letter of 13.05.2005

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☒ the claims, Nos. 18-20
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6-8, 10-11, 15, 17
	No:	Claims	1-5, 9, 12-14, 16
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-17
Industrial applicability (IA)	Yes:	Claims	1-17
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V.

1 The following documents are referred to in this communication. The documents D9 and D10 were not cited in the international search report. Copies of the documents are appended hereto.

D6 : US 2 897 118 A (ALLEGRETTI JOHN E) 28 July 1959 (1959-07-28)
D9: WO 01 74175 A (AUSTRALIAN FOOD INDUSTRY SCIEN [AU]; COMMW SCIENT & IND RES ORGANIS [AU]) 3 April 2001 (2001-04-03)
D10: US 5 143 737 A (THOMAS RICHARDSON) 1 September 1992 (1992-09-01)

2 Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 and 16 is not new in the sense of Article 33(2) PCT.

The document D9 discloses a stable powderous formulation comprising a fat in a matrix of milk protein thermally cross linked with a reducing sugar, the powder being suitable for food or feed use (see D9: examples 7 - 9, 13).

3 Inventive step

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 15 and 17 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D9 discloses a stable powderous formulation comprising a fat in a matrix of partially hydrolysed milk protein (casein) thermally cross linked with a reducing sugar, the powder being suitable for food or feed use (see D9: examples 7 - 9, 13). The subject-matter of claim 15 differs form the teaching of the document D9 merely in that the amount of hydrolysis is specified. The specified range however forms part of the state of the art. The document D6 discloses a powdered Vitamin A composition which contains cross linked hydrolysed casein with a degrees of hydrolysis of 1-10% (see D6: column 1, line 25-27; column 3, line 25-42 and examples). It may therefore by considered normal procedure

for those skilled in the art to select this range without exercising any inventive activity. Furthermore, since the application as filed contains no disclosure relating to the special or unexpected properties pertaining to this particular range of hydrolysis relative to the rest of the range, then it appears that this range is a mere selection, without inventive character and therefore the subject-matter of claim 15 lacks inventivity.

The document D10 discloses a method for preparing an animal feed product which comprises the steps of preparing an aqueous emulsion of the fat soluble ingredient (an unsaturated lipid) and the milk protein composition, adding the reducing sugar, heating the mixture in order to crosslink the protein and there after freezing drying the mixture, implicitly forming a powder (see D10: example 1). The subject-matter of claim 17 differs from the teaching of the document D10 in that the steps of crosslinking and forming the powder are in a different order. It is unclear however, if there is any technical effect accruing to this inversion of the steps. For this reason it is unclear as to what inventive character claim 17 may possess.

4 Dependant Claims

Dependent claims 2-14 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

Novelty

Claims 2-5 are disclosed in the document D9 which refers to the use of caseinate. Claims 9 and 14 relate to the reducing sugar e.g. glucose, fructose etc. although these are disclosed in the prior art. Novelty is removed from the subject-matter of claims 12 and 13 by the teachings of the prior art (see D9: examples).

Inventive Step

Claims 6 - 8 relates additionally to the use of plant protein or mixtures and/or their degree of hydrolysis although it appears that such compositions are known alternatives to the use of milk proteins and their use or partial substitution would be easily envisaged by those

skilled in the art. Claim 10 and 11 refer to adjuvants such as silica although their incorporation in such compositions is standard practice in the art.

What is claimed is:

1. Stable powderous formulations comprising a fat-soluble active ingredient in a matrix of a milk protein composition, wherein the protein is thermally cross-linked with a reducing sugar or a reducing sugar derivative.

2. Formulations according to claim 1, wherein the milk protein composition is a native milk protein or partially hydrolyzed milk protein with a degree of hydrolysis of up to 25% or mixtures thereof having a protein content of more than 80 wt.-%.

3. Formulations according to claim 1, wherein the milk protein composition is a native milk protein or partially hydrolyzed milk protein with a degree of hydrolysis of up 15 % or mixtures thereof having a protein content of more than 80 wt.-%.

4. Formulations according to claim 1, wherein the milk protein composition is a native milk protein or partially hydrolyzed milk protein with a degree of hydrolysis of up 10 % or mixtures thereof having a protein content of more than 80 wt.-%.

5. Formulations according to any one of claims 1 to 4, wherein the milk protein is a caseinate or partially hydrolyzed caseinate.

6. Formulations according to any one of claims 1 - 5, wherein the milk protein composition contains additionally a plant protein or plant protein hydrolysate or mixture thereof.

7. Formulations according to claim 6 wherein the average molecular weight of at least 80 % of the plant protein hydrolysate is below 2500 Daltons.

8. Formulations according to claims 6 or 7, wherein the plant protein or plant protein hydrolysate is obtained from potato protein, soy protein, wheat protein, pea protein, rice protein or lupin protein.

9. Formulations according to any one of claims 1 - 8, wherein the milk protein composition contains additionally a carbohydrate or carbohydrate derivative, e.g. saccharose, invert sugar, glucose, fructose, xylose, lactose, maltose, xanthan gum, acacia gum, pectins, guar, caroub gums, alginates, celluloses, cellulose derivatives, starch, modified starch and starch hydrolysates, such as dextrins and maltodextrins, especially such in the range of 5-65

dextrose equivalents (hereinafter: DE) and glucose syrup, especially such in the range of 20-95 DE.

10. Formulations according to any one of claims 1 - 9 further comprising an adjuvant.

11. Formulations according to claim 10 wherein the adjuvant is calcium silicate, silicic acid, starch or calcium carbonate, or mixture thereof.

12. Formulations according to any one of claims 1 - 11, wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid, or esters thereof,or mixtures thereof.

13. Formulations according to claim 12, wherein the fat-soluble active ingredient is mixed with a plant or animal oil or fat, e.g. sunflower oil, palm oil or corn oil.

14. Formulations according to any one of claims 1 - 13, wherein the reducing sugar is glucose, fructose, saccharose or xylose.

15. Stable powderous formulations comprising a fat-soluble active ingredient in a matrix of a milk protein composition, wherein the milk protein is a partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25%.

16. Food, beverages, animal feeds, cosmetics or drugs comprising a formulation according to any one of claims 1 - 15.

17. Process for the preparation of formulations according to any one of claims 1 - 14, which comprises preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding a reducing sugar or a reducing sugar derivative, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein by heat treatment.